

## REMARKS

In response to a Second Notice of Non-Compliant Amendment mailed January 20, 2004, the withdrawn claims now have text. The undersigned appologizes for the omission of the text, but was relying on the instructions in the O.G. o f 2/25/03 that indicated that withdrawn text should be omitted. Apparently that is no longer the rule.

### Rejections Based on 35 USC § 112

2.a. The Examiner has objected to Claim 1 as lacking an antecedent basis for the language "all cones positioning their respective windows at the same distance from said imaging device" and questions how it is possible for all the cone windows to be at the same distance from the imaging device, when there is a distance between the outer window 147 and the inner window 133. The claim however is not describing the outer an inner window, nor is it describing the separate inner cone. The claim refers to a cone having "a transparent window for bearing against an area of skin", which is clearly a reference to the outer window of the front cone 145 and not the inner cone 133. The claim describes a hand-held unit that has two or more cones, each of which has an outer window. It is those outer windows that bear against the skin and are at the same distance from the imaging device. The inner window which the Examiner correctly pointed out as being at a clearly different distance from the imaging device is part of an internal cone that "serves to protect the video camera" from dust and other pollution including immersion fluid. It is not one of the imaging cones that bears against an area of skin. With this explanation it should be apparent that Claim 1 does not lack an antecedent basis and is not indefinite.

2.b. The previous argument thus also responds to the rejection of claims 2-20 as dependent upon Claim 1.

2.c. The Examiner states that there is no antecedent basis for the reference to “one cone has multiple colours around its transparent window permanently”. Claim 1 refers to cones, each having a transparent window. The phrase “multiple colors” does not require an antecedent because it is a new element in this claim. Similarly, the reference to being permanently in the field of view is a new element and does not require an antecedent to its recitation. It is assumed that the Examiner’s point is that he does not find support in the specification for the use of multiple colors, but finds only a reference to white material. The specification states, however, at page 19, line 23, that “They may be of a range of colors, including either all white, or white, light grey, dark grey and black, or some other combination.” Thus the term color, as used in this specification is used to include, in addition to white, grey scale elements, and of course other colors. This supports the reference to multiple colors. This also explains the reference to multiple colors around its transparent window, as seen for example in Fig. 7A, where around the transparent window are the “targets” having different grey scale elements.

2.d, e, f. These paragraphs contain the same rejections already discussed and are dealt with by the same remarks.

2.g. The Examiner rejected claim 61 because it refers to “a plurality of reference targets of known colours on an outer surface”. The use of materials that are placed on

the patient side of the window is detailed in the descriptions of Figures 7A, 7B, 7C and 7D. It is in that section that the relevance of the use of multiple colors is explained. Figure 7A, in particular, shows how different colors are used in each corner of the field of view. It is important to appreciate that the use of the word "colors" is naturally intended to include the use of various shades of grey and not the narrower meaning of the word. Again, with the understanding that the known colors includes grey scale elements, and in view of the disclosure accompanying Fig. 7A, this feature is adequately supported in the specification.

2.h, i. These paragraphs contain the same rejections already discussed and are dealt with by the same remarks.

#### Rejections Based on 35 USC § 102

3. The Examiner has rejected claims 1, 7-8 and 18 as anticipated by Binder. Claims 7-8 and 18 are dependent from claim 1, and therefore an explanation of lack of anticipation of claim 1 suffices to deal with all four claims.

One of the unique aspects of this invention is the provision of multiple cones. The Examiner found two cones in Binder by a reference (col. 12, line 28) to a lens housing section 410 having a polarization foil 610, which the Examiner interpreted to be an alternative cone. These elements may be seen in Binder Fig. 5 (labeling the element 410) and Binder Fig. 7 (labeling the element 610). As may be understood from these figures, the lens housing section 410 and the polarization foil 610 are not components of a cone, but are internal structures separate from what could be described as Binder's

cone element. Thus there is no anticipation of the claim requirement for separate cones. In this regard it should be noted from the disclosure of the present invention, particularly the description of Fig. 2, that the front cone is distinguished from the internal elements such as the inner cone and window 133, and is not a description of everything that could be housed within the hand held unit.

The use of multiple cones having different purposes is novel and is an important distinguishing feature of this invention. One of the special features of this invention is that it enables reproducible images of lesions to be gathered over periods of many years. This is achieved by means of the elaborate and meticulous attention to detail that has been found to be required. The measurement of color and of light in general is an extremely exacting science and what appear to be minor details in the device make a major difference between the special precision of this invention and the prior art. Multiple cones are therefore needed to set up and to maintain the calibration of the instrument to the exacting standards needed to achieve reproducible images. Stability of the image is important to the effectiveness of this invention because the most sensitive means for detecting the presence of a melanoma on a patient is the detection of minute changes in the optical properties of the patient's lesions. These changes often defy detection by eye but this invention, because of its stability and reproducibility is able to reliably detect them.

#### Rejections Based on 35 USC § 102

4.a The Examiner has combined Binder with Gutkowicz-Krusin to reject claims 2-4.

As already explained, Binder does not provide the multiple cones limitation. Gutkowicz-

Krusin do not provide the additional limitation of a cone having multiple colors around its transparent window, etc. Instead, as the Examiner recognizes, Gutkowicz-Krusin provides several narrowband filters. These cannot be considered to be the same as the multiple colors required by the claim, for the following reason. The multiple "colors" of the present invention are reference targets painted onto the face of the window that is pressed onto the patient's skin. They do not filter the light but simply reflect a portion of the white light as corners of the image projected into the imaging device. They are not color filters. They do not modify the light that is used to illuminate the lesion. They do not modify the light reflected by the lesion on its way to the imaging device. They are not related to the filters used by Gutkowicz-Krusin. Contrary to the suggestion of the Examiner one of ordinary skill would not have been motivated to provide grey scale for example in the corners of the image by the concept of filtering the examining light for its different frequency components. These are different concepts.

4.b The Gutkowicz-Krusin invention as described in Section 4.b. attempts to draw a parallel with the configuration of the present invention. There is no mention in the Gutkowicz-Krusin specification of targets placed on the skin or on the skin side of the window. Therefore it has no relevance to the present invention. Gutkowicz-Krusin has filters in the illuminating light source but that is irrelevant to present Claim 3.

4.c A similar juxtaposition has occurred in Section 4.c, where the presence of a blanking disc at the light source is analogized to the use of a target of known reflectance that is fitted in front of the imaging device as a reference calibration material. The

Gutkowicz-Krusin use of a blanking disc is related to setting the reference black level of the signals. Video cameras produce some signals even without light entering them and this needs to be measured and subtracted from the measuring signals. This is not the signal that is referred to in our Claim 4 which is a measure of the top end sensitivity of the imaging device, not the black level.

5.a Binder and Van Heuvelen are applied to rejections of claims 9-10. Those claims are however dependent from claim 1 and therefore for the reasons given why claim 1 is not anticipated by Binder claims 9-10 are not made obvious in view of the combination.

6.b, c Binder alone, with suggestions of what would have been obvious without the citation of specific references, is asserted to make obvious claims 19-22 and 64-65. The principal argument is that thickness of the windows is merely a matter of design choice that does not have a material effect on the performance of the invention. This suggestion overlooks one of the important distinguishing features of this invention. The specification details at some length the relevance of the total internal reflection (TIR) behavior of the window and how this must be taken into account and controlled. If a window of one thickness is used for calibration or standardization and a different thickness is used for imaging the skin, the brightness will be seriously in error. The magnitude of this effect was not understood by those who created the prior art and that is why this invention is such a significant advance on the state of the art.

6.d, e. By employing windows of not less than 5 millimeters the TIR effect is

enormously reduced, far more than one would expect intuitively. Moreover in the current embodiment of the invention the thicker window makes the effect traceable with the corner targets and hence compensatable. By painting the edges of the window black as has been detailed in the specification, the light that would have found its way back to the lesion during a measurement is effectively absorbed. Brightening of the lesion image by the light reflected from the surrounding skin is thereby avoided so that the quality of the image is not compromised as occurs with other devices such as Binder's. This use of a thicker than normal window is one of the many creative aspects of this invention. It can be seen that the choice of window thickness is not to be taken lightly but is in fact an integral part of the optical system. If the image were merely to be observed by a human operator, the change of brightness would not figure so dominantly. In the case of this invention precise optical measurements of brightness are essential for the computer to assist with the diagnosis by detecting subtle changes with time. Therefore all factors that affect that lesion brightness must be controlled and those factors include the window thickness. It is not "simply a matter of design choice". It is an integral feature of this invention.

6.f. Section 6 . f. reads into Binder's specification material that is simply not there. While Binder clearly houses and seals the front window of his device, no attention is given to ensuring that the edges are not reflective. We have found that this aspect of the invention must be given careful attention. Our studies have shown that the use of apparently identical, to the eye, black materials to seal the edges can lead to changes in the optical behavior of the window. The edges must be truly light absorbing and not

simply housed in some unspecified material that seals them against the ingress of oil or other materials.

7-8. Claims 13-17 are dependent from claim 1 and are not made obvious in view of the combination of references cited for the reasons given with respect to claim 1. Claims 23-29 have been canceled, and therefore the rejection with respect to them is now moot.

9. Binder and Van Heuvelen are applied to rejections of claims 11/9, 11/10, 12/9 and 12/10. Those claims are however dependent from claim 1 and therefore for the reasons given why claim 1 is not anticipated by Binder claims 9-10 are not made obvious in view of the combination and neither are these multiply dependent claims from claim 1.

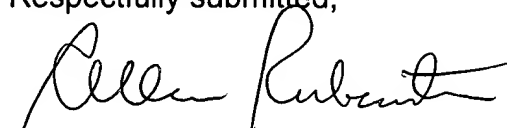
10. The Examiner has combined Takamura with Binder to reject claims 5-6 and 61-63. The Examiner acknowledges that Binder lacks the plurality of reference targets of known colors and attempts to supply that element through Takamura's use of a protective layer on the glass. In order to do this the Examiner repeats his understanding that the specification disclosed only one color (white) and that therefore it is not necessary to deal with more than one. This is incorrect for the reason already given in explaining how the term color is used in the specification. Furthermore, the use by Takamura for a coating bears no relation to the purpose of the reference targets; i.e. the coating does not provide reference targets. Thus the referenced claims are not in



any way made obvious by the cited combination of references.

For the reasons stated, the application is now in a condition for allowance.

Respectfully submitted,

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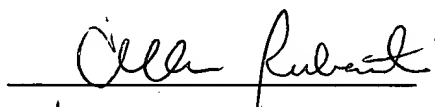
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Dated: January 29, 2004

CERTIFICATE OF MAILING

I hereby certify that the enclosed correspondence relating to patent application  
Serial No. 09/473,270, filed 12/27/1999, is being deposited with the United States  
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A handwritten signature in dark ink, appearing to read "Allen Rubenstein", is written over a horizontal line.

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